REMARKS

Claims 1-17 are pending in the application.

Reconsideration and review of the claims on the merits are respectfully requested.

Double Patenting Rejection

A. Claims 1-17 are rejected under the judicially created doctrine of double patenting over claims 1-12 of U.S. Patent No. 6,837,244.

B. Claims 1-17 are provisionally rejected under the judicially created doctrine of double patenting over claims 1, 4-10, 12, 14-22 and 24-32 of copending Application No. 09/956,925.

Applicants respond as follows.

Applicants file two Terminal Disclaimers concurrently herewith to overcome the double patenting rejections.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the double patenting rejections.

Response to Claim Rejection - 35 U.S.C. § 102(b)

Claims 1-17 are rejected under under 35 U.S.C. §102(b) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as being obvious over Levy et al. (US 4,340,044).

Regarding independent claim 1, the Examiner cites Levy et al. as disclosing an oxygen supply apparatus which supplies oxygen or oxygen-enriched gas to a user having a breathing cycle including an inhalation period and an exhalation period synchronously with breathing of

the user by means of a breath synchronization function, as shown in Figure 1, which comprises: a sensor (62, 63) for detecting the state of breathing of the user; means 1 for judging the state of breathing of the user under a predetermined judgment condition when breath-synchronized operation is performed, based on a signal from the sensor; and means (1, 56) for supplying oxygen or oxygen-enriched gas to the user over a predetermined period of time when no breathing is detected, based on a time period of between 0 to 40% of inspiratory time, as depicted in the Table in column 14.

The Examiner recognizes that Levy et al. does not disclose that the predetermined period of time is specifically in the range of 2.15 to 4.8 seconds, but asserts that it would be obvious, if not inherent, given the physiological factors of respiration as recited in the Table in column 14, to use this particular time period.

Levy et al. fails to anticipate or render obvious the present invention for the following reasons.

Levy et al. describes ventilator equipment for use by patients requiring mechanical ventilatory assistance. Levy's exemplary ventilator is equipped for three modes of operation, namely a standby mode, a control mode and an automatic mode. In the standby mode, the ventilator functions to monitor a patient inhalation and exhalation, breathing rate and other parameters without delivering gas/oxygen to the patient. In the control mode, the ventilator automatically delivers to a patient a prescribed minute volume of an air/oxygen mixture at a preset respiration rate and inspiration-to-expiration ratio. Finally, the automatic mode delivers a mandatory minute volume to a patient, assuring that the patient has adequate ventilation at all

times even if his or her own respiratory drive ceases completely (see col. 1, line 59 to col. 2, line 12).

For the automatic mode of operation, the patient is enabled to breathe spontaneously from the gas mixture stored in the continuous positive airway pressure (CPAP) bellows, and the automatic mode control facilities automatically inform the control module whether such patient breathing is within or without a desired range (col. 3, lines 42-47). The bellows assembly is flexible for receiving and storing a gas mixture and for supplying that mixture under a constant positive airway pressure to the patient breathing passageway via the gas flow control apparatus (col. 3, lines 18-23). Accordingly, the control module identifies when the CPAP bellows is excessively filled due to a patient breathing much less than the desired spontaneous range (see col. 4, lines 38-40). Thus, Levy's volume ventilator apparatus relies on volume changes in the bellows to control the flow of oxygen to the patient.

In Levy, when the CPAP bellows is excessively filled due to a patient breathing much less than the desired spontaneous range, the control module is automatically switched from the automatic to the control mode to supply the mandatory minute volume for patient breathing (column 4, lines 38-45). This is again repeated at column 13, lines 51-53, which describes that "if the patient breathes very little or not at all, bellows 76 fills to a level which causes the ventilator tow to switch automatically to its control mode of operation". This is the mode of operation corresponding to the situation treated by the present invention "when no breathing is detected".

Levy et al. handles the situation by switching from automatic to control mode. As discussed above, in control mode the ventilator automatically delivers to a patient a prescribed

minute volume of an airless oxygen mixture at a preset respiration rate and inspiration-to-expiration ratio (column 2, lines 3-7). That is, in control mode, the apparatus forces breathing at a prescribed volume and preset respiration rate. This is distinguished from automatic mode where the patient triggers the inspiration, and, as needed, the ventilator increases the depth of the breath in synchronism with the patient's breathing (column 13, lines 40-43).

On the other hand, Applicants claim an oxygen supply apparatus including means for supplying oxygen or oxygen-enriched gas to the user over a predetermined period of from 2.15 to 4.8 seconds when no breathing is detected. Although Levy et al. discloses the concept of taking some concrete action when the command center indicates that the volume in the bellows is excessive, indicating that breathing has stopped or slowed to a predetermined amount, namely switching to control mode, this is different from supplying oxygen or oxygen-enriched gas to the user over a predetermined period as required by the present claims. Thus, the present invention differs from Levy et al. in that oxygen or oxygen-enriched gas is supplied to the user over a predetermined period (nominally, four (4) seconds and with a range of 2.15 to 4.8 seconds) when no breathing is detected (See page 4, lines 8-11 and page 6, lines 13-16 of the specification), whereas in Levy et al., the apparatus switches to control mode to force breathing at a prescribed volume and preset rate. The present invention quickly comes to the aid of a patient when there is either a breathing anomaly based on a time range or a malfunction in the sensor (page 4, lines 12-14 of the specification), and more importantly, without wasting oxygen or oxygen-enriched gas, whereas that is not the case in Levy et al.

The difference is that in the present invention, oxygen is supplied for a short, predetermined period when no breathing is detected, wherein as in Levy, the apparatus goes into

control mode to force repeated respiration when no breathing is detected. In this manner, the oxygen supply apparatus of the present invention does not waste oxygen or oxygen-enriched gas, while still ensuring a high degree of safety.

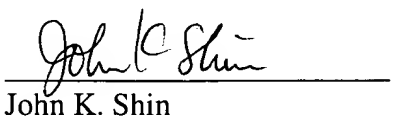
The Examiner points to the inspiration plateau of 0-40% as shown in Fig. 10 as rendering obvious the claimed predetermined period of from 2.15 to 4.8 seconds. However, the two values have nothing to do with one another. The inspiration plateau of 0-40% of the table at column 14, more particularly, is the length of the inspiratory pause shown in Fig. 10. This is a dial control on the apparatus which presumably allows the doctor to fine tune to the respiration cycle of the patient. On the other hand, the range of 2.15 to 4.8 seconds is derived based on the breathing rate (5 to 7 times/min.) and the fraction of the breathing cycle attributable to inspiration. This is how the predetermined period of time is set. There is no connection between the two values as suggested by the Examiner.

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the rejections based on Levy et al.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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